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APPENDIX 8.

Quest International, Inc., 1938 N.E. 148th Terrace, N. Miami, FL 33181
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510(k) SUMMARY

Applicant: Quest International, Inc.
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Date prepared: December 26, 1995

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Device: SeraQuest™ Toxoplasma IgG

Device Classification: Class II (performance standards)

Device Name: Toxoplasma serological reagents (21CFR § 866.3780)

Description:

The SeraQuest™ Toxoplasma IgG test is a solid phase enzyme immunoassay (EIA), which is performed in microwells, at room temperature, in three thirty-minute incubations. It has been developed to detect IgG antibodies which are directed against Toxoplasma gondii in human serum.

Principle:

Diluted samples are incubated in antigen-coated wells. Toxoplasma antibodies (if present) are immobilized in the wells. Residual sample is eliminated by washing and draining, and conjugate (enzyme-labeled antibodies to human IgG) is added and incubated. If IgG antibodies to Toxoplasma are present, the conjugate will be immobilized in the wells. Residual conjugate is eliminated by washing and draining, and the substrate is added and incubated. In the presence of the enzyme, the substrate is converted to a yellow end product which is read photometrically.

Intended Use:

For the detection of human IgG antibodies to toxoplasma virus in human serum by enzyme immunoassay, to aid in the serological assessment of single samples and the diagnosis of primary infection in paired sera through the detection of seroconversion of Toxoplasma specific IgG antibody. These reagents have not received FDA clearance for use in testing blood or plasma donors.

Predicate device:

The SeraQuest™ Toxoplasma IgG test has been shown to be substantially equivalent to the Toxoplasma IgG Clin-ELISA™ kit, INCSTAR Corporation, Stillwater Minnesota.

Summary of technological characteristics:

<u>Characteristic</u>	<u>SeraQuest™ Toxoplasma IgG</u>	<u>INCSTAR Toxo IgG Clin-ELISA™</u>
Description:	Enzyme Immunoassay	Enzyme Immunoassay
Intended Use:	The detection of IgG antibodies against <i>Toxoplasma gondii</i> in human serum.	The detection of IgG antibodies against <i>Toxoplasma gondii</i> in human serum.
Antigen Strain	RH	RH
Solid Phase:	Plastic Microwell	Plastic Microwell
Number of Incubation Periods:	Three	Three
Sample Dilution:	1:51	1:51
Sample Volume:	100 µl	200 µl
Sample Incubation Duration:	30 minutes	30 minutes
Incubation Temperature:	Room temperature	Room temperature
Enzyme-labeled Conjugate:		
Antibody	Goat anti-human IgG	Goat or Sheep anti-human IgG
Enzyme	Alkaline phosphatase	Alkaline phosphatase
Conjugate Volume:	100 µl	200 µl
Conjugate Incubation Duration:	30 minutes	30 minutes
Substrate:	p-Nitrophenyl phosphate	p-Nitrophenyl phosphate
Substrate Volume:	100 µl	200 µl
Substrate Incubation Duration:	30 minutes	45 minutes
Stop Reagent:	0.5 M Trisodium phosphate	3 N Sodium Hydroxide

Stop Reagent Volume:	100 μ l	50 μ l
Readout:	Spectrophotometric 405 nm	Spectrophotometric 405 nm

Summary of Clinical Testing:

One hundred and forty-three sera from normal blood donors were assayed for the presence of Toxoplasma IgG antibodies, using the SeraQuest™ Toxoplasma IgG test and the INCSTAR Toxoplasma IgG Clin-ELISA™ test. Of the one hundred and forty-three specimens tested, forty-one were positive, and ninety-six were negative, by both tests. Of the six remaining specimens, three were positive in The SeraQuest™ test and negative in the comparative test, one was positive in the SeraQuest™ test and equivocal in the comparative test, and two specimens were equivocal in the SeraQuest™ test and negative in the comparative test. Excluding the equivocal results, the sensitivity and specificity, of the SeraQuest™ test relative to the INCSTAR Toxoplasma IgG Clin-ELISA™ test, was 98.8 % to 100 % (95 % C.I.) and 93.6 % to 100 % (95 % C.I.), respectively. The overall agreement was 95.5 % to 100 % (95 % C.I.). These results are shown below in Table 1.

Table 1. Results of Comparative Testing of 143 Serum Specimens, Using the SeraQuest™ Toxoplasma IgG Test and the INCSTAR Toxoplasma IgG Clin-ELISA™ Test.

INCSTAR Toxoplasma IgG	SeraQuest Toxoplasma IgG			95 % Confidence Interval*
	Positive	Equivocal	Negative	
Positive	41	0	0	Relative sensitivity√ 98.8 to 100
Equivocal	1	0	0	
Negative	2	3	96	Relative specificity√ 93.6 to 100
				Overall agreement√ 95.5 to 100

√ Excluding equivocal results.

* Calculated by the normal method.